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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,837	06/25/2001	Anand V. Gumaste	MICRODOSE 00.01	9414

7590 08/13/2003

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EXAMINER

PATEL, NIHIL B

ART UNIT	PAPER NUMBER
3743	14

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/888,837	GUMASTE, ANAND V.
	Examiner	Art Unit
	Nihir Patel	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on Amendment/RCE filed on July 23<sup>rd</sup>, 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,3,5 and 8-15 is/are pending in the application.

4a) Of the above claim(s) 5 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3 and 8-15 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Election/Restrictions*

1. Claim 5 is hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected species or inventions, there currently being no allowable generic claim or linking claim. Election was made with traverse.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisele et al. US Patent No. 5,921,237. Referring to claim 1, Eisele discloses a dry powder inhaler that comprises an elongate flexible tape 194 (see figures 20 and 22, column 4 lines 1-5) having spaced areas 198 (see figures 20 and 22, column 3 lines 60-67), and a frangible second element overlying the first element and defining a plurality of spaced top crowned areas located over the first element spaced areas, and containing powder or liquid material (see column 3 lines 60-67 and column 4 lines 48-50), wherein the contents of the blister are forcibly ejected from the blister when the spaced areas are interfaced coupled with the vibratory de-aggregator (see column 4 lines 36-45).

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The intended use statements are not given any patentable weight in this instance for example “for interfacing and coupling with the inhaler vibratory de-aggregator”.

Referring to claim 3, Eisele discloses top crowned areas that are shaped as inverted cones (see figure 22).

Referring to claim 8, Eisele discloses a material that comprises a medication (see column 4 lines 48-50).

Referring to claim 13, Eisele shows that the size and number of holes together with volume formed by the blister pack are optimized for de-aggregation and aerosolization of material in the blister pack.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The intended use statements are not given any patentable weight in this instance for example “for de-aggregation and aerosolization of material in the blister pack”.

Referring to claim 14, Eisele shows that the height and shape of the blister pack is optimized for de-aggregation and aerosolization of material in the blister pack.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The intended use statements are not given any patentable weight in this instance for example “for de-aggregation and aerosolization of material in the blister pack”.

Referring to claim 15, Eisele shows that the interface to the vibrator is optimized for optimum coupling of the energy into the blister pack for de-aggregation and aerosolization of material in the blister pack.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The intended use statements are not given any patentable weight in this instance for example “for de-aggregation and aerosolization of material in the blister pack”.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 5,921,237 in view of Pera U.S. Patent No. 5,944,012.

Eisele discloses the applicant’s invention as claimed with the exception of stating that the material comprises a vitamin.

Pera discloses a method for dispensing antioxidant vitamin by inhalation background of the invention that does state that the material comprises a vitamin. Therefore it would be obvious to modify Eisele’s invention by stating that the material comprises a vitamin so that one knows the limitations of the invention.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Hendricks U.S. Patent No. 5,699,789.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a hormone or a steroid.

Hendricks discloses a dry powder inhaler that does state that the material comprises a hormone or a steroid. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a hormone or a steroid so that one knows the limitations of the invention.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Shyjan U.S. Patent No. 6,312,909.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a bioactive material.

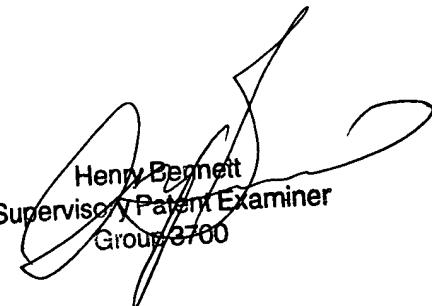
Shyjan discloses a compositions and methods for the diagnosis prevention and treatment of tumor progression that does state that the material comprises a bioactive material. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a bioactive material so that one knows the limitations of the invention.

*Conclusion*

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP  
August 4, 2003



Henry Bennett  
Supervisory Patent Examiner  
Group 3700